ISRCTN00075564 https://doi.org/10.1186/ISRCTN00075564

A trial of withdrawal of nocturnal non-invasive positive pressure ventilation (NIPPV) in chronic obstructive pulmonary disease (COPD) patients with chronic hypercapnic ventilatory failure previously stable on nocturnal NIPPV

Submission date 23/05/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/07/2005	**Overall study status** Completed	
Last Edited 16/07/2010	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Nick Oscroft

Contact details
Papworth Hospital NHS Trust
Papworth Everard
Cambridge
United Kingdom
CB3 8RE
+44 (0)1480 830541

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
04/Q0104/139 - NRR Publication ID: N0542155456

Study information

Scientific Title

Study objectives
Currently it is unclear whether patients with severe COPD benefit from noninvasive positive pressure ventilation in the long term. There is divided opinion and evidence on whether this is a beneficial treatment and who might benefit. In performing this clinical trial of withdrawal of a non-proven treatment with close monitoring we plan to address the issue of whether of not the treatment does maintain the patients in a stable clinical state and improve their quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic Obstructive Pulmonary Disease (COPD)

Interventions
Comparison of withdrawing long term NIPPV treatment or continuing

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
'Withdrawal Failure' as stipulated by preset criteria. The effect of withdrawal of NIPPV therapy on arterial blood gas analysis.

Criteria for Withdrawal Failure:
1. Daytime PaCO2 >9 kPa
2. Nocturnal PtcCO2 >10 on night study
3. Respiratory acidosis pH <7.35
4. Intolerable symptoms, including morning headache and drowsiness

Secondary outcome measures
1. Assess the effect of withdrawal of NIPPV therapy on: quality of life using SF-36 and St George's respiratory questionnaire, exacerbation rates, hospital admissions, GP contact and requirements for treatment with antibiotics and steroids
2. Assess that if preset criteria are met, reinstitution of NIPPV therapy has positive effects
3. Measure changes to spirometric, mouth pressure data and exercise capacity

Overall study start date
16/05/2005

Completion date
31/01/2007

Eligibility

Key inclusion criteria
Pre-screening criteria:
1. Diagnosis of COPD: forced expiratory volume in 1 second (FEV1) <50% predicted, FEV1/forced vital capacity (FVC) ratio <70%, total lung capacity (TLC) >80% predicted
2. Smoking history >20 pack years
3. Prior to commencing NIPPV hypercapnic ventilatory failure with daytime PaCO2 >7.5 kPa with normal pH (7.35-7.45) or nocturnal PtcCO2 >9 kPa
4. On NIPPV for at least 3 months with compliance of >4 hours/day
5. Live within 40-mile radius of trust

Screening criteria:
1. Clinically stable - no increase in breathlessness, cough or sputum volume in 4 weeks between initial assessment and entry to trial
2. PaCO2 within +/-1 kPa of initial assessment
3. No change in spirometry (<15% or 200 ml) from initial assessment

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Age over 80
2. Other significant respiratory disease (interstitial lung disease, asthma, bronchiectasis, neuromuscular or restrictive chest wall disorders)
3. Significant documented left ventricular dysfunction with Ejection Fraction <40%
4. Obstructive sleep apnoea with an apnoea/hypopnoea index of over 10, which is reversible by continuous positive airway pressure (CPAP)

Date of first enrolment
16/05/2005

Date of final enrolment
31/01/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Papworth Hospital NHS Trust
Cambridge
United Kingdom
CB3 8RE

Sponsor information

Organisation
Papworth Hospital NHS Trust (UK)

Sponsor details
Papworth Everard
Cambridge
England
United Kingdom
CB3 8RE
+44 (0)1480 830541
diane.bilton@papworth.nhs.uk

Sponsor type

Hospital/treatment centre

ROR
https://ror.org/01qbebb31

Funder(s)

Funder type
Industry

Funder Name
Respiratory Support and Sleep Centre Trust fund supported by an unrestricted grant from B & D Electromedical (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2010		Yes	No